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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,418	09/10/2003	Gregory M. Glenn	056707-5001-01	3179

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,418	GLENN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,8,11,13-16,18 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7,8,11,13-16,18,26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4, 5, 7, 8, 11, 13-16, 18 and 26-28 are pending.

2. Applicant's species election with traverse in the reply filed on 9/13/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

Applicants' request of rejoinder of species upon allowance of generic claim is acknowledged.

Accordingly, claims 1, 4, 5, 7, 8, 11, 13-16, 18 and 26-28 read upon species of chemical indicator are under consideration in the instant application.

3. Applicants' IDS filed on 1/27/04 is acknowledged.

4. Applicants' claim for domestic priority under 35. U.S.C. 119 (e) is acknowledged. However, the non-provisional applications (08/749,164 and 08/896,085) failed to provide adequate written support under 35. U.S.C.112 for claim limitation of "marker or marking formulation" of the claimed invention, the support for the limitation found on the provisional application (60/137,790) and the priority date of instant application is deemed to be 6/3/99.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant is requested to identify the written support for the claimed limitation of " chemical indicator" and "marking formulation" (in claim 1(d)) and "readily discernable by visual or olfactory senses" in claim 7.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4-5, 7, 8, 11, 13-16, 18, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The specification does not reasonably provide enablement for a method of inducing an immune response comprising applying a formulation to more than one application site and site overlying more than one draining lymph node.

The antigenic stimulation at an application site results the lymph collected is filtered through a set of defined lymph nodes of the local area. Distal and multiple applications of antigens to cervical and abdomen areas would not result one draining lymph node (Kuby, 2000, Immunology, 4th ed. p. 47-53).

Furthermore, the specification does not reasonably provide enablement for a method of inducing an immune response without any forms of pre-treatment to break the skin. In order to induce an antigenic specific immune response transcutaneously, one must break skin with abrasive, add penetrating chemical, or hydration and occlusion to disrupt natural, physical and chemical barrier of skin. The intact skin serves physical and anatomic barriers that prevent entry of pathogens (Kuby, 2000, Immunology, 4th Ed, p. 7, 8, 57).

Thus, Applicant has not provided any guidance to enable one skill in the art to use claimed invention in manner reasonably correlated with the scope of enablement. In view or the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4, 7 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Glenn et al. (Infection and Immunity 67(3): 1100-1106, IDS reference).

Glenn et al. teach transcutaneous immunization in animals with bacterial ADP-ribosylating Exotoxin including cholera toxin and diphtheria toxin as antigens and adjuvants (p. 1101-1102).

Glenn et al. further teach I-125 association of antigen (p. 1103, i.e. radioactive tag) which works as an indicator.

As Applicants fail to define "readily discernable indication" of chemical indicator, I-125 activity can be visually monitored, claim 7 is included in this rejection. Thus, the reference teachings anticipate the claimed invention.

10. Claims 1, 4, 5, 7, 8, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by the U.S. Pat. No. 4,152,412 (IDS reference).

The '412 patent teaches an immunization of animals with antigen (i.e. Brucella abortus, tetanus toxoid, col. 2, lines 13-20) and chemical indicator (i.e. dye, coloring, fluorescent materials, charcoals, col. 1, lines 30-63).

The '412 patent further teaches the chemical indicator provides indication of the length of time to which the subject has exposed to the formulation (col. 1, lines 41-45) and colored formulation could serve indication of release of the agent over time (col. 4, lines 35-40).

As is evidenced by the specification of the instant application, p. 4, lines 6-15 and p. 2 lines 21-25, tetanus toxoid can be both antigen and adjuvant, the reference formulation meets the claimed invention. The claim 8 is included in this rejection because applicants fail to provide the definition of "deactivate said antigen" and interpreted to mean "depletion or exhaust" of antigen over time. Thus, the reference teachings anticipate the claimed invention.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 4, 5, 7, 8, 11, 13-16, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,152,412 (IDS reference) in view of U.S. Pat. No. 5,667,798 (IDS reference).

The teachings of '412 patent have been discussed, supra.

The '412 patent does not teach a use of applicator (i.e. patch) or pretreatment including washing.

However, the '798 patent teaches an applicator such as a transdermal patch comprising various drug formulations and multi-color indicators that designed to change over time, dose delivery, controlled release or color change when the drug formulation has been depleted (Summary, col. 2, lines 16-63, col. 6, lines 39-51).

The '798 patent further teaches a controlled release (col. 2, lines 41-44), gel (col. 4, lines and hydration (i.e. washing, col. 1, lines 63-65). The reference applicator provides indication of degree of hydration of skin surface when patch is removed, useful for administering any drug formulations to children and convenient to use (col. 2 –3 overlapping paragraph, co. 4, lines 1-15).

Therefore, one of the ordinary skill in the art would have been motivated to combine the vaccine formulation taught by the '412 patent to the drug applicator with multi-color indicator taught by the '798 patent because the transdermal drug applicator with multi-color indicator is useful for administering drugs to children, easy to use and the color indicator assures dose delivery.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,152,412 (IDS reference) and U.S. Pat. No. 5,667,798 (IDS reference) in view of U.S. Pat. 3,901,158.

The teachings of the '412 and '798 patents have been discussed, supra.

The '412 patent or '798 patent does not teach use of air gun.

However, the '158 patent teaches the use of air gun type hypodermic projectile provides an easy method of administering drug without use of needles (col. 1, lines 20-25, col. 4, lines 4-15).

Therefore, one of the ordinary skill in the art would have been motivated to combine the air gun type hypodermic projectile taught by the '158 patent in the vaccine formulation with color indicator taught by the '412 patent and '798 patent because the air gun type hypodermic projectile provides an easy method of administering drug without use of needles.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. No claims are allowable.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 17, 2005

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